IN 2005 the European Clinical Research Infrastructures Network (ECRIN) launched what was to become an annual event to commemorate International Clinical Trials Day that is celebrated internationally on the 20 May. On 20th May 1747, James Lind (Scottish naval surgeon), embarked on a Controlled Clinical Trial of 12 scurvy sailors on board the ship named Salisbury, James Lind is regarded as the first known Clinical Trial man and his Controlled Clinical Trial involving 12 sailors diagnosed with scurvy, were administered with the following interventions:

- 2 sailors received oranges and lemons
- 2 sailors received cider
- 2 sailors received vinegar
- 2 sailors received elixir virzol
- 2 sailors received concoction of spices, garlic and mustard seeds
- 2 sailors received sea water

Six days later, the two sailors receiving oranges and lemons became well. A major breakthrough for an anti-experiment of scurvy who identified sailors were henceforth given oranges and lemons to prevent scurvy. Such dramatic intervention effects supported by trials are very rare. However, the outcome of this Clinical Trial illustrates the power of a Clinical Controlled Trial that enables empirical evidence of an intervention where the outcome/s of an intervention/s is uncertain or unknown.

Today’s, Clinical Trials are based on scientific principles (comprised of 5 phases; i.e. Pre-clinical studies - Phase 0; Phase 1; Phase 2; Phase 3; and Phase 4) and are far more sophisticated it is complicated with a ‘built in’ component of ethics. Before any Clinical Trial can commence the proposal of the Clinical Trial has to be reviewed and approved by the Ethics Committee where researchers have to ensure that participants in the Clinical Trial would be required to give informed written consent to be able to participate in the Clinical Trial and that patients have an option to opt out of the Clinical Trial at any time they wish.

However, long before James Lind, more than 10 centuries ago, an eminent Islamic medical scholar, Ali Ibn Sina Balkhi, known in the West as Avicenna (981-1037AD), was acknowledged as one the greatest thinkers and medical scholars in history for his treatise on cardiac drugs, contagious nature of tuberculosis (TB), distribution of disease by water and soil and clear description of sexual diseases. His book titled the Canon of Medicine was based on the combination of the Greek and Arabic experiences. Islamic medicine, the writings of the Roman physician Galen, the Indian physicians Shushra and Charaka, and ancient Arabian and Persian texts as aspects of Chinese medicine.

The Canon is considered one of the most famous medical books in medical history and is considered to be the first pharmacopoeia. Among Ali Ibn Sina Balkhi’s many other medical contributions, the Canon is known for the introduction of scientific methodology and the integration of Evidence-Based Medicine, Experimental Medicine, Clinical Trials, Randomized Controlled Experiments into the study of Physiology, the discovery of the contagious nature of infectious diseases, as well as the idea of a syndrome in the diagnosis of specific disease, etc.

The Canon was used at many medical schools in Europe as late as 1650 and as well as a medical reference source as early as the 19th Century. The Canon had set medical standards In the Islamic World as well as Europe especially during the Dark Ages. Much of the Canon was translated into Chinese by the Hui people of Yuan in China, and the Canon became the basis for Unani Medicine (traditional medicine) that is practised to this day in India. Principles of medicine as described in the Canon are to this day being taught in the course related to History of Medicine at UCLA and Yale University in United States.

With such overwhelming medical contributions by Ali Ibn Sina Balkhi, known in the West as Avicenna (981-1037), especially in the field of Medical Experimentation and Clinical Trials, which history bears adequate testimony to this fact, this has unfortunately been placed by many into the dustbin of history. True few ideas in the world of research are entirely original. However, in the case of Medical Experimentation and Clinical Trials, Ali Ibn Sina Balkhi (Avicenna) proposed the idea of an intervention which came to fruition (7 centuries later) with James Lind’s first recorded Controlled Clinical Trial of sailors with scurvy in 1740.

So next year (in 2010) when we commemorate International Clinical Trials Day - a thought should be given to Ali Ibn Sina Balkhi whose idea of Clinical Trial and Medical Experimentation came to full fruition with James Lind’s Controlled Clinical Trial of oranges and lemons that compared other controlled interventions that were administered to sailors with scurvy. This event thus marked the beginning of era of Clinical Trials.

Random Clinical Trials (RCT) are regarded as the Rolls Royce of epidemiological study design that elicits difference between people compared or difference in the manner treatment outcomes are assessed. Sackett proposes that the practice of Evidence Based Medicine is the integration of individual clinical expertise on systematic research and review. The British epidemiologist, Archie Cochrane who founded the Cochrane Database of Systematic Reviews in 1993 (with its Cochrane Central Register of Controlled Trials) is available internationally as Evidence Based Medicine.

Today, Clinical Trials are bound to various codes of conduct i.e. Clinical Trial Resolutions such as the 5th World Health Assembly (WMA) Resolution of 2005 which called on global scientific community as well international partners and stakeholders: “to establish a network linking of international clinical trials registers in order to ensure a single point of access and the unambiguous identification of trials”.

This resolution is further strengthened by the Helsinki Declaration (2000) which states: “The principles, risks, burdens and benefits of the research method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. At the conclusion of the study, every patient entered into the study should be assured of access to the best proved prophylactic, diagnostic and therapeutic methods identified by the study.”

The objective of International Clinical Trials Day is not only to celebrate James Lind’s first Clinical Trial (and hopefully in 2010 and thereafter, it will include Ali Ibn Sina Balkhi) but also to highlight the improvement of patients’ and public health awareness on the various challenges confronted by health scientists when conducting Clinical Trials, Hence, this International Clinical Trials Day is marked by encouraging stimulating debates, meetings and discussions among patients’ associations, clinical/public health scientists, scientific agencies, ethics committees, health science journal editors, donor agencies, trial registries as well as relevant stakeholders.

Finally, it would be apt to conclude with the announcement in the recent publication in the New England Journal of Medicine, of a new ‘wonder drug’ Clinical Trial for the treatment of multi-drug resistant TB, which has shown to cure multi-drug resistant TB patients much faster as compared to the treatment for current multi-drug resistant patients. This ‘wonder drug’ TMC207 (dubbed ‘J’) is still in the Clinical Trial phase, and if approved it will be the first new TB drug developed in the past 40 years. The results show that 48% of the enrolled multi-drug resistant TB patients who were administered TMC207 showed to be non infectious after 8 weeks as compared to 9% for multi-drug resistant patients on TB drugs without TMC207. It takes 6 months to cure a TB patient and at least 18 months to cure multi-drug resistant TB patients. So if this TB Clinical Trial of TMC207 (J), conducted at 4 South African hospitals, spearheaded by University of Stellenbosch, is successful in Phase 4, it will mark a new era in the treatment of multi-drug resistant TB, in South Africa and indeed it will be a major breakthrough in the context of global TB drugs. Here again are the foundations, contributions and implementation of Ali Ibn Sina Balkhi’s and James Lind’s beginnings of Clinical Trial coming to greater fruition after more than 10 centuries.